UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ZAMBON GROUP S.p.A., Plaintiff, v. PFIZER, INC., WARNER-LAMBERT, L.L.C., and GOEDECKE AKTIENGESELLSCHAFT, Defendants.	:	Civ. Action No.: 03-5334(JCL) **MEMORANDUM AND ORDER**

LIFLAND, District Judge

Defendants Pfizer, Inc., Warner-Lambert, L.L.C., and Goedecke Aktiengesellschaft ("Warner-Lambert") move to dismiss the Complaint of Plaintiff Zambon Group S.p.A. ("Zambon") in its entirety. Counts I and II of the Complaint allege antitrust violations. Counts III-V of the Complaint seek a declaratory judgment of non-infringement, invalidity, and unenforceability of Warner-Lambert's U.S. Patent No. 6,054,482 ("the '482 patent"). For reasons explained herein, the Court will grant the Motion to Dismiss Counts III-V and will stay its consideration of the Motion to Dismiss the antitrust claims.

BACKGROUND

On April 17, 1998, Apotex Corp. ("Apotex") filed an Abbreviated New Drug Application (ANDA) seeking F.D.A. approval to market a generic capsule version of Warner-Lambert's drug Neurontin®. On June 13, 2000, nearly two months after Warner-Lambert's '482 patent issued, Apotex submitted a Paragraph IV certification asserting that its generic gabapentin capsule products would not infringe the '482 patent. On July 20, 2000, Warner-Lambert sued Apotex for patent infringement.

On February 14, 2002, Apotex submitted an amendment to its ANDA identifying Zambon as an alternate supplier of bulk gabapentin for use in Apotex's formulated capsule products.[1] Given Zambon's role as a bulk gabapentin supplier, Warner-Lambert took discovery regarding Zambon's gabapentin and the process for making it.

Zambon manufacturers the bulk gabapentin for Apotex in Italy. Zambon does not sell that bulk gabapentin in the United States. At the time of briefing, Zambon intended to sell its bulk gabapentin to Apotex in Canada, where Apotex has a facility to mix the bulk gabapentin. (Calcagno Supp. Decl., Ex. 3).

[1]Apotex initially identified Teva Pharmaceutical Ltd. ("Teva") as their supplier of bulk gabapentin. Because Teva not only supplied bulk gabapentin, but also had filed ANDAs seeking approval to market its own formulated gabapentin capsule and tablet products, Warner-Lambert sued Teva for infringement of the '482 Patent. Warner-Lambert did not bring suit against Teva based on its status as a bulk gabapentin supplier.

'482 Patent

Claim 7 of the '482 patent, the only independent product claim, covers a pharmaceutical composition containing gabapentin:

> 7. A stable and pure pharmaceutical composition in unit dry medicinal dosage form consisting essentially of:
>
> (i) an active ingredient which is gabapentin in the free amino acid, crystalline anhydrous form containing less than 0.5% by weight of its corresponding lactam and less than 20 ppm of an anion of a mineral acid and
>
> (ii) one or more pharmaceutically acceptable adjuvants that do not promote conversion of more than 0.2% by weight of the gabapentin to its corresponding lactam form when stored at 25°C and an atmospheric humidity of 50% for one year.

('482 Patent, col. 8, ll. 29-40 (emphasis added)). Claims 8-11 depend from claim 7 and, therefore, incorporate all the limitations of claim 7, including the "less than 20 ppm" limitation.

Bulk gabapentin, such as that supplied by Zambon, is used as the "active ingredient" of the formulated pharmaceutical composition.

ANALYSIS

A. Declaratory Judgment

The Declaratory Judgment Act provides, in relevant part:

> In a case of actual controversy within its jurisdiction . . . any court of

> the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought.

28 U.S.C. § 2201(a).

The existence of an actual controversy is a necessary prerequisite for Article III jurisdiction. Aetna Life Ins. Co. v. Haworth, 300 U.S. 227, 239-40 (1937); Spectronics Corp. v. H.B. Fuller Co., Inc., 940 F.2d 631, 633-34 (Fed. Cir. 1991). The declaratory judgment plaintiff bears the burden of proving that an actual controversy exists between the parties. Carpet Group Int'l v. Oriental Rug Importers, 227 F.3d 62, 69 (3d Cir. 2000). Where there is no actual controversy, a court has no discretion to decide the case on its merits and is compelled to dismiss the action. Spectronics Corp., 940 F.2d at 634.

Whether an actual controversy exists depends on "the totality of the circumstances." Id. There is a two-pronged test for ascertaining whether an actual controversy exists:

> (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit, and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity.

Phillips Plastics Corp. v. Kato Hatsujou Kabushiki Kaisha, 57 F.3d 1051, 1052 (Fed.

Cir. 1995) (quoting BP Chemicals Ltd. v. Union Carbide Corp., 4 F.3d 975, 978 (Fed. Cir. 1993)).

B. Patent Allegations

Counts III-V of the Zambon Complaint seek a declaratory judgment of non-infringement, invalidity, and unenforceability of the '482 patent.

Warner-Lambert moves to dismiss the patent claims for lack of subject matter jurisdiction, arguing that there is no actual controversy between the parties. Warner-Lambert maintains that it has done nothing to create a reasonable apprehension on the part of Zambon because Zambon's gabapentin, taken alone, cannot infringe the '482 patent claims, which are directed to a fully-formulated pharmaceutical product containing gabapentin as the active ingredient and that there is no suggestion that Zambon will engage in any act that would constitute infringement.

Zambon maintains that is has a "reasonable apprehension" of being sued by Warner-Lambert for inducing infringement of the '482 patent. Its rationale is that if Warner-Lambert had proper claims for infringement against Apotex, it may also have a claim for infringement against Zambon, given that one who "actively induces infringement of a patent shall be liable as an infringer," 35 U.S.C. § 271(b), and one who makes a product that does not have a substantial non-infringing use can be liable for contributory infringement, id. § 271(c).

Three reasons are offered in support of Zambon's "reasonable apprehension" argument: (1) Warner-Lambert brought patent infringement suits against Zambon's customers; (2) Warner-Lambert brought suit for patent infringement against Zambon in Italy over the European counterpart to the '482 patent; and (3) Warner-Lambert accused Zambon of infringement in an April 29, 2003 letter addressed to Magistrate Judge Falk that stated:

> If Zambon's gabapentin contains large amounts of sodium and potassium, it is most likely an indication that the chloride ion in Zambon's gabapentin is non-acidic–e.g., the chloride ion comes from sodium or potassium chloride. If this is the case then Zambon's gabapentin infringes the '482 patent's "less than 20 ppm of an anion of a mineral acid" limitation regardless of its chloride ion level.

(4/29/03 Barrett Ltr. at 5). Zambon also asserts that it may be sued for infringement of claim 1 of the '482 patent, which covers a process for making the gabapentin compound.

Warner-Lambert argues that the "inducing infringement" theory is not alleged in the Complaint and, in any event, no actual controversy exists under that theory because Apotex's potentially infringing sales are highly speculative. According to Warner-Lambert, Zambon cannot be sued for inducing an artificial act of infringement occasioned by Apotex's ANDA filing and its Paragraph IV certification because it was not involved in that act of infringement. That is, Zambon was not

Apotex's bulk drug supplier at the time Apotex submitted its ANDA, nor was it Apotex's supplier at the time Apotex submitted its Paragraph IV certification. (Calcagno Supp. Decl. at ¶¶3-4). Warner-Lambert further argues that Apotex has no firm entry date into the market and it is uncertain whether Apotex will ever use Zambon's gabapentin, instead of gabapentin supplied by others. Warner-Lambert thus characterizes this action as an attempt on Zambon's part to obtain an advisory opinion concerning events that are speculative, at best.

Warner-Lambert addresses each of the reasons cited by Zambon in support of its "reasonable apprehension" of being sued. First, Warner-Lambert argues that the fact that Warner-Lambert has sued other generic drug manufacturers has no bearing on a potential suit against Zambon. The key is that in no other circumstance has Warner-Lambert brought suit against a supplier that has not, itself, sought to market a fully-formulated gabapentin product. Further, Zambon cannot infringe process claim 1 of the '482 patent because Zambon performs that process in Italy and does not sell its bulk gabapentin to Apotex in the United States. The relevant statute, 35 U.S.C. § 271(c),[2] provides that contributory infringement depends on the infringer

[2]35 U.S.C. § 271(c) states:
Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a

offering to sell or import its product into the United States.

Second, as to the Italian litigation, Warner-Lambert emphasizes that Zambon does not intend to sell a formulated drug product that infringes the patent and has engaged in no U.S.-based activities that would constitute infringement.

Third, Warner-Lambert's letter to Judge Falk did not charge that Zambon's bulk product infringed the '482 patent. Rather, the letter stated that Zambon's gabapentin might meet a limitation or element of a claim of the patent. Zambon cannot infringe the patent product claims, given additional limitations that have no applicability to Zambon's bulk gabapentin.

Finally, Warner-Lambert argues that even if there is an actual controversy here, the Court should exercise its discretion to decline declaratory judgment jurisdiction. See Wilton v. Seven Falls Co., 515 U.S. 277, 282 (1995). That is because Zambon's declaratory judgment suit involves the same issues as those in the underlying suit against Apotex. All of the infringement issues relating to Apotex's formulation, including whether Zambon's bulk gabapentin meets the "less than 20 ppm of an anion of a mineral acid" limitation of claim 7, will be resolved in the suit against Apotex. Warner-Lambert contends that this

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staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.

duplication of effort and resources can be avoided if the Court declines jurisdiction over Zambon's declaratory judgment action. And, although Zambon points out two non-duplicative issues–a non-infringement defense regarding process claim 1 and an inequitable conduct/invalidity defense based on Warner-Lambert's clinical testing of gabapentin–that does not merit the exercise of jurisdiction.

Zambon filed a Notice of Subsequent Events (Praecipe), addressing Warner-Lambert's statement in its reply brief that "it is far from clear whether Apotex will ever even use Zambon's gabapentin." (Warner-Lambert Reply Br. at 10). Zambon argues that Warner-Lambert's statement is contradicted by a June 9, 2004 Warner-Lambert letter stating that "Apotex purchases its gabapentin active ingredient from Zambon, an Italian Corporation." (June 9, 2004 Barrett Ltr. at 2). This contradiction undercuts Warner-Lambert's argument that Apotex's potentially infringing sales using Zambon's gabapentin are speculative, but, as discussed below, the Court does not find this point to be determinative.

The Court concludes that there is no actual controversy here to support declaratory judgment jurisdiction. Zambon's arguments concerning its "reasonable apprehension" of being sued by Warner-Lambert are not persuasive. The fact that Warner-Lambert has brought patent infringement suits against other

generic manufacturers, none of whom have the same supplier-only status as Zambon, does not signal an infringement suit against Zambon in its capacity as a supplier.

As to the Italian litigation, courts have come out differently on whether suit or threat of suit in a foreign forum on a corresponding foreign patent is sufficient to satisfy the reasonable apprehension requirement. Teva Pharmaceuticals USA, Inc. v. Abbott Laboratories, 301 F.Supp.2d 819, 822 (N.D. Ill. 2004). The inquiry is fact specific. The Court adopts the view that while foreign litigation is not dispositive of a reasonable apprehension of suit in the United States, it is nonetheless a factor to be weighed in the analysis. See Teva Pharms. USA Inc. v. Abbott Labs., 301 F. Supp. 2d 819, 822 (N.D. Ill. Jan. 12, 2004). Here, the Italian litigation involving Warner-Lambert and Zambon does not necessarily signal an infringement suit against Zambon in the United States, particularly given that such a claim would be tied specifically to Zambon's activity in the United States. Finally, the Court is not persuaded that the letter sent to Judge Falk by Warner-Lambert's counsel rises to the level of an express charge of infringement. The letter plainly describes the potential for Zambon's gabapentin to read on part of claim 7, assuming certain conditions are met, and not infringement of the '482 patent.

Even were the Court to conclude that there was an actual controversy supporting declaratory judgment jurisdiction here, the Court would decline to exercise it due to the significant overlap of issues with pending motions and potential duplication of effort. As Warner-Lambert points out, infringement issues relating to Apotex's formulation, including whether Zambon's bulk gabapentin meets the "less than 20 ppm of an anion of a mineral acid" limitation of claim 7 of the '482 patent, will be resolved in the pending suit against Apotex.

C. Antitrust Allegations

Zambon also asserts claims for monopolization and attempt to monopolize under Section 2 of the Sherman Act, 15 U.S.C. § 2. The first of these claims asserts that Warner-Lambert "with full knowledge that all claims of the '482 patent are invalid and unenforceable . . . [brought] a baseless infringement action against Zambon's customer, Apotex/Torpharm" and "sued or threatened to sue virtually every generic manufacturer that attempted to enter the relevant market." (Compl. ¶¶ 154-55). The second claim asserts that Warner-Lambert violated the antitrust laws "[b]y initiating and/or prosecuting its baseless actions against Zambon's customers and/or threatening Zambon's customers with infringement actions even though [D]efendants knew or should have known that the '479, '476, and '482 patents were not infringed by Zambon's gabapentin." (Compl. ¶ 163).

Warner-Lambert moves to dismiss the antitrust claims on the ground that Zambon cannot allege the essential element of antitrust injury and that, even if Zambon could establish that element, its claims still must be dismissed for lack of antitrust standing under the multi-factor analysis set forth by the Supreme Court in Associated Gen. Contractors, Inc. of Cal. v. Cal. State Council of Carpenters, 459 U.S. 519, 539-46 (1983). Those factors include (1) directness of the injury; (2) the existence of more direct victims; (3) a causal connection between the antitrust violation and the harm to the plaintiff; and (4) the potential for duplicative recovery or complex apportionment of damages.

The antitrust injury argument goes that Zambon, as a supplier of bulk gabapentin, does not compete in the market for the dosage forms of gabapentin used to treat patients. Zambon does not allege that it has ever filed an ANDA seeking F.D.A. approval to market the dosage forms of gabapentin that are provided to patients. Rather, it seeks to sell its bulk gabapentin product to generic companies that have filed such ANDAs. The argument continues that Zambon has been injured, if at all, only as a result of its customers' exclusion from the market and that damages would be complex and speculative given that Zambon must show (1) which generic manufacturers would have chosen it as their supplier instead of other bulk suppliers, (2) the amounts of the bulk gabapentin these manufacturers would have purchased

from Zambon, and (3) its lost profits on those sales.

Alternatively, Warner-Lambert argues that Zambon's antitrust claims, if not dismissed outright by the Court, should be severed and stayed pending resolution of the underlying patent infringement claims on which they are based. Zambon agrees that its antitrust claims should be stayed. (Zambon Opp. at 2 ("Zambon agrees with Warner-Lambert that the Court should stay the antitrust claims.")).

The Court need not resolve Warner-Lambert's motion to dismiss the antitrust claims at this juncture. The Court has already stayed related antitrust claims by Order dated October 29, 2002, and it is appropriate to do so here. Resolution of the patent claims might support or eliminate Zambon's antitrust claims, or at least inform the Court's assessment of such claims. The Court will revisit the Motion to Dismiss the antitrust claims once the underlying patent claims are resolved.

Accordingly, **IT IS** on this 26th day of May 2005,

ORDERED that Warner-Lambert's Motion to Dismiss Counts III-V of Zambon's Complaint, seeking a declaratory judgment of non-infringement, invalidity, and unenforceability of the '482 patent is granted; and it is further

ORDERED that the Court's consideration of the Motion to Dismiss Counts

I and II of Zambon's Complaint shall be stayed pending resolution of Warner-Lambert's patent infringement suit against Apotex Corporation.

/s/ John C. Lifland, U.S.D.J.